

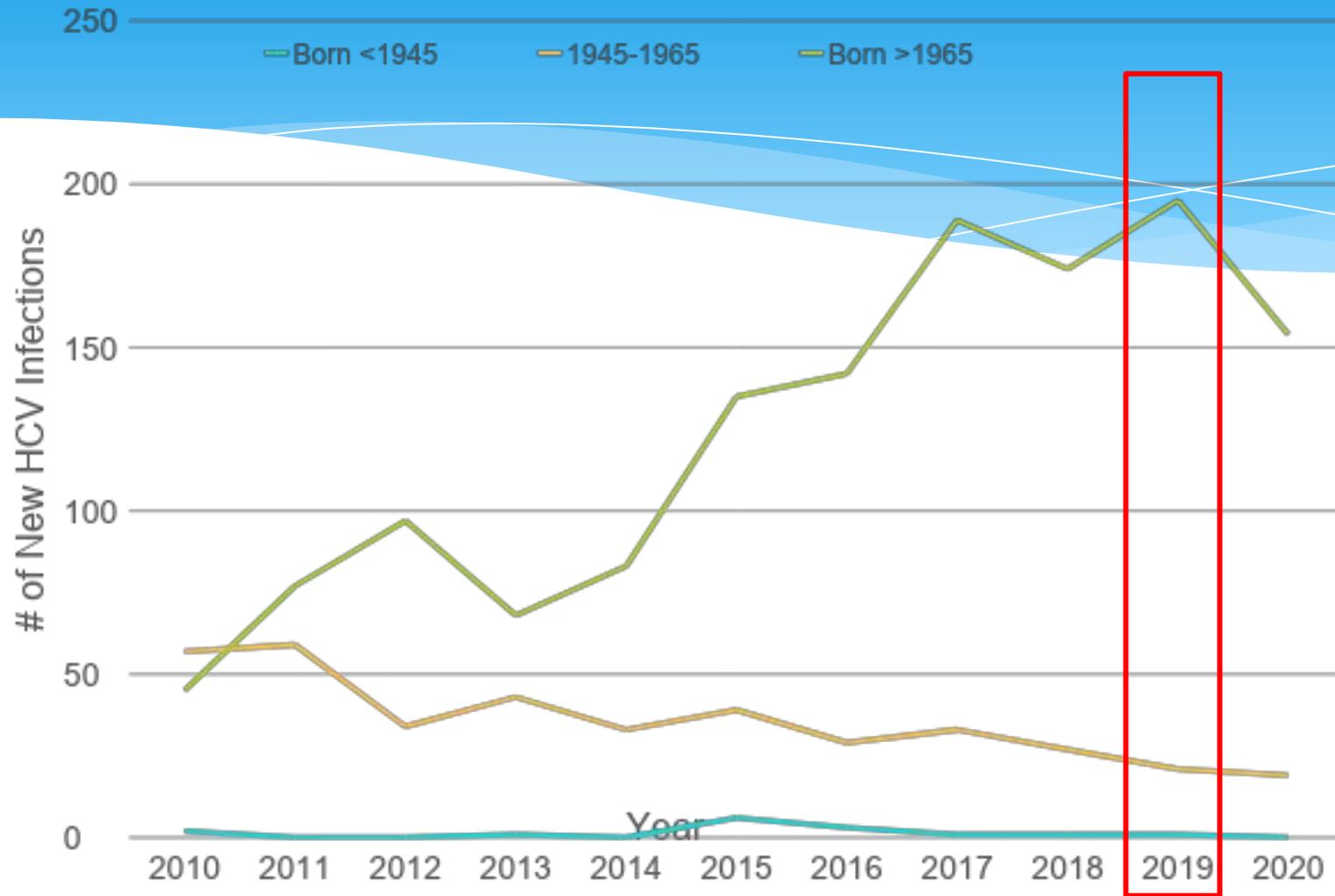
A Study to Evaluate Screening and Treatment for Hepatitis C in Remote Alaskan Communities

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Hepatitis C Epidemic in Alaska

- * Hepatitis C is a viral infection of the liver that can lead to cirrhosis, cause the liver to fail and liver cancer in persons who have this infection
- * Most persons who have hepatitis C are not sick until their liver fails or they get liver cancer.
- * Alaska Native (AN) Persons have among the highest rates of hepatitis C in the US
- * AN Persons have the highest rate of liver cancer of any racial/ethnic group in the US: the rate of liver cancer has doubled in the last 20 years primarily due to hepatitis C
- * Hepatitis C is spread by blood contact and is most common in persons who inject drugs but before 1990, many persons got hepatitis C from other sources including tattooing, blood transfusion, medical procedures, body piercing, or other blood exposures because precautions to prevent this infection were not standard

New Confirmed HCV Cases for Alaska Natives from 2010-2020 by Generation



All Adults in the US are now Recommended to be Screened for Hepatitis C

- * The CDC recommends that all adults ages 18 to 80 years old be screened one time for hepatitis C
- * The reason is that many were infected before we knew this virus existed and before the current universal precautions to prevent infections were recommended, including screening blood for transfusions, using clean needles for tattooing and body piercing, wearing gloves for dental and other procedures

The Good News: Hepatitis C Can Now be Cured!

- * Since 2015, oral drugs have been available that cure 95% of persons with hepatitis C with just 8 to 12 weeks of once a day medication
- * These medicines have no serious side effects
 - * About a third of persons experience a mild headaches, some tiredness or occasional upset stomach

Hepatitis C Treatment Revolution

Short
Treatments

>95%
cure for
most

Once
daily
dosing

Few Side
effects

Minimal
monitoring

Medications for Hepatitis C: It's as easy as these 3

Glecaprevir/pibrentasvir
(Mavyret)

Ledipasvir/sofosbuvir (Harvoni)

Sofosbuvir/velpatasvir (Epclusa)



HCV in Alaska Native (AN) People

- * Over 1,000 AN persons have been treated with DAA; Sustained Virologic Response or cure rate in AN persons is >90%
- * 600 in Anchorage
 - * DAA treatment transitioned in Anchorage to SCF using pharmacists in the primary care
- * 400 in Tribal Health Organizations hospitals and clinics where a provider is available

Which Alaska Native Persons with Hepatitis C are Getting Treated and Cured

- * Anchorage, are now primarily treated by SCF/Pharmacy
 - * Persons with cirrhosis are treated at the liver clinic
- * Regional THO Hospitals and Clinics are actively treating persons with hepatitis C
- * However, persons living in remote communities off the road system are for the most part, not getting treated:
 - * We have identified already 184 AN persons living in rural communities needing treatment
 - * Many barriers to accessing treatment as they need to make 2 to 4 trips to the nearest facility with licensed provider by plane often > 100 miles away to be treated

Where is Hepatitis C Found In Alaska?



Bringing HCV Screening and Treatment to Persons Living in Isolated Rural Communities: One Stop Shopping

- * Design a program to train Community Health Aide/Providers to screen persons in their communities for hepatitis C and treat via telemedicine with specialists at ANMC
 - * CHA/P AN persons who receive 16 week program and are certified by the State of AK
 - * CHA/P would screen all residents 18 to 80 years old using rapid HCV test
 - * Those positive would have blood drawn and serum sent for HCV virus
 - * Those positive for HCV viral RNA would be treated via telemedicine and tested 12 weeks after completion for test of cure
 - * Rates of cure would be compared to rates obtained in rural communities with those found in the Hepatology specialty clinic at the ANMC to test null hypothesis which means no difference in cure rates
- * We have received funding for a Pilot Study from CDC to include 10 rural communities : we are applying for a large Grant to expand project to 40 communities.

On Site Testing for Hepatitis C

- * Availability of point of care rapid finger stick tests
 - * OraQuick rapid anti-HCV test
 - * CLIA waived
 - * Billable
 - * Results in 20 minutes
 - * If positive need to draw a blood to sent to ANMC for HCV RNA

Fingerstick

Step 1 -
Collect Specimen & Mix in buffer



Step 2 -
Insert device into buffer



Step 3 -
Read between 20 and 40 minutes



Non-Reactive
Line in the C Zone

Reactive
Line in the C & T Zones

Venipuncture Whole Blood

Step 1 -
Collect Specimen & Mix in buffer



Step 2 -
Insert device into buffer



Step 3 -
Read between 20 and 40 minutes



Non-Reactive
Line in the C Zone

Reactive
Line in the C & T Zones

One Stop Shopping for Persons Living in Rural Communities

- * Pilot project funded by CDC for 5 communities in Yukon Flats villages
- * One and ½ day training program for CHAP and regional providers and Tribal Leaders
- * CHA/P would screen all adults 18-79 one time with the OraSure rapid test both AN and Non-Native persons. Incentive for CHA/P
- * Those positive for anti-HCV would have blood drawn and sera sent to ANMC lab for HCV RNA to test for liver virus
- * Those HCV RNA+ would be offered treatment via monthly telemedicine visits with ANTHC Liver Program Provider
- * Regional provider would fill out prior authorization or forms for free drug from company and write prescription

Every Person can be Treated at no or Minimal Cost to them or THO's

- * Testing for Hepatitis C is reimbursed by Alaska Medicaid, Medicare, and Private Insurances
- * Pharmaceutical Assistance Programs to Cover Those Uninsured or Who Cannot Afford Copayments so Tribal Health Organizations do not have to pay for these drugs.

www.abbvie.com/patients/assistance

www.mysupportpath.com

- * Medications are purchased through VA system and cost about 75% of the amount reimbursed by Medicaid

In Conclusion

- * We are proposing to conduct a study after obtaining IRB and Tribal approval to test all adults living in rural communities for hepatitis C and if positive, offer treatment in their community clinics overseen by CHA/P via telemedicine with specialists at the liver clinic at ANMC
- * We will compare the cure rates obtained in rural community clinics to the cure rates at ANMC liver clinic and predict that there will not be a significant difference found.